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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/592,032

Applicant(s)

JUNKER ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DTAILED ACTION

Applicants' request for the extension for three months filed 18 June 2002 (Paper NO. 4) has been entered.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-14 and 19, filed on 18 January 2002 (Paper NO. 5) is acknowledged. In view of Applicants' election, Claims 15-18 are withdrawn from consideration as directed to non-elected invention. Therefore, Claims 1-14 and 19 are pending and examined in this Office Action.

The instant application Claim 19 recites a "use". Applicant is reminded that "use" claims are non-statutory and are not appropriate for US practice (see MPEP 2173.05(q)). For examination purposes "use" claims are interpreted as a method of the first recited "use".

Claims 15-18 are directed to a product, i.e. hGH crystal. Pursuant to the procedures set forth in the *Official Gazette* notice dated March 26, 1996 (1184 O.G. 86), claims 1-14 and 19 directed to the process of making or using the product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 1-4 and 19 hereby rejoined and fully examined for patentability under 37 CFR 1.104. Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Paper No. 5 is hereby withdrawn.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Denmark on July 13, 1990. It is noted, however, a copy of 1687 90 application in

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English, or a certified copy of 1687/90 application if not written in English has not been filed as required by 35 U.S.C. 119(b).

Object to IDS

Please note that Applicants' submission of IDS filed 9 June 2000 is incomplete since it contains no legible copies of each U.S. and foreign patent and each publication or that portion which caused it to be listed as cited in the list of the submitted IDS. Thus, it fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C (1).

Objection to Specification

The disclosure is objected to because of the following informalities:

(1) In page 1, line 21, the term "Met-hGH" needs to be spelled out fully for the first time, and in which "hGH" is unclear as to what it refers to.

(2) In page 10, line 20, "Zn(Ac)" is unclearly presented since the abbreviation "Ac" can be referred to a symbol for actinium or allyl chloride. It is advised to be changed to zinc acetate or $\text{Zn}(\text{CH}_3\text{CO}_2)_2$.

(3) In bridging pages 11-12, the recitation "F-7 and F-8" needs to be clarified.

(4) In page 13, line 15, "10%" should be changed to "10% (v/v)" for consistency.

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Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, Claim 15 also, GH should be spelled out in full at first recitation in each independent claim. Claim 1 is indefinite in the recitation of "...from about 0% to about 30 % ...", because it is ambiguous as to what are encompassed in these limitations. The recitations appear to set a " \pm " parameter on both ends of the % temperature range permitting GH crystal growth. It therefore would result in a vague and unpredictable range for using claimed growth condition that is critical for uniformity, size, stability and yield of resultant crystal. It is also unclear as to whether are the "known means" to which the claim refers. Dependent claims are also rejected. Claim 6 and 14 are indefinite as the same reason stated above.

Claim 1 is also indefinite as to what are or are not "GH derivatives".

Claim 3, a Markush-type claim, recites the term "or" that renders the claim indefinite because it is unclear what are the "short chained aliphatic", and "cyclic", which are separate members of the Markush group as currently recited.

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A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2, 7, 12 and 17 recites the broad recitations pH 5.8 to 6.5; concentration of 0.1 to 30%; 1.0 to 3.0 mol Zn^{2+} /mol GH; and molar ratio between Zn^{2+} and GH is from about 0.2 to about 10; respectively, and the claims 2, 7, 12 and 17 also recite pH 6.0 to 6.5; concentration of 0.1 to 20%, 5 to 15% and 6 to 12%; 1.1 to 2.2 mol Zn^{2+} /mol GH and 1.2 to 2.0 mol Zn^{2+} /mol GH; and molar ratio between Zn^{2+} and GH is from about 0.5 to 5 and 0.5 to 20; respectively, which are the narrower statements of the range/limitation in respect to each claim.

Claim 5 recites the term "or" that renders the claim indefinite. The claim recites that organic solvent is ethanol or acetone; but which one is used ethanol or acetone?

Claim 8 is indefinite as to a multiply dependent claim that depends that depends from another multiple dependent Claim 6. See also Claims 13, 14, 18 and 19.

Claim 10 is indefinite as to what is "unspecific precipitation" and what is the "amorphous material".

Claim 13 recites the limitation "growth hormone" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 and 15 recite "derivatives": there is no context of any proceeding term(s); it is therefore unclear as to what are derivatives referred to.

Claim Rejection, 35 U.S.C. 101, Double Patenting

Claims 2, 3, 4, 5, 6, 7, 8-9, 11, 12, 13, 14 and 16 are rejected under 35 U.S.C. 101 as claiming the same invention as claims 11, 2, 3, 4, 5, 6-8, 13, 14, 15-17, 10, 12 and 19 of U.S. Patent No. 5,780,599, respectively. This is a double patenting rejection.

Claim Rejection –Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 1-19 are rejected under the judicially created doctrine of the obviousness-type double patenting of Claims 1-23 in United States Patent 5,780,599. Although the conflicting claims are not identical, they are not patentably distinct from each other.

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Claim 1 of the instant application is identical to US 5780599 expect pH range between 5.0 and 6.8 (the instant application) and between 5.8 and 6.5 (the reference patent). This minus difference of pH value does reflect no subject matter difference since the present application sets forth that the pH is most preferably from 5.0 to 6.8 (see column 2, line 59).

Claim 8 of the instant Application discloses use of divalent cation for production of GH crystal which is virtually set forth in Claims 1-a) and column 2, line 63 of US 5780599.

Claim 10 of the instant application sets forth the condition for addition of the zinc ion into the solution; US 5780599 Claim 15, especially column 3 lines 1-5, disclose the same subject matter.

Claim 14 of the instant application sets forth that use of the claimed crystallization process as a purification and/or isolation step in manufacturing GH. Accordingly, US 5780599 discloses the same (see the first sentence of Claim 1, and especially, column 3, lines 62-63).

Claim 17 of the instant application discloses the molar ratios between Zinc ion and GH. Accordingly, US 5780599 teaches the same limitation of the molar ratios (see claim 22 and column 3, lines 32-42).

Claim 18 of the instant application sets forth a pharmaceutical preparation. Accordingly, US 5780599 teaches the same (see claim 23 and especially, column 3, lines 54-62).

Note that Claim 19 is also a non statutory claim recites a "use"; "a use" is not a statutory claim of invention.

Therefore, the claims stated above in the instant application and those in US 5780599 disclose the same and/or common subject matter.

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

It is noted that page 22 of the response filed 3 January 2002 requests abeyance of the obvious-type double patenting rejection until allowable subject matter is indicated. Note that no allowable subject matter can be indicated with a standing ground of rejection. Thus, it is suggested that applicant file the appropriate terminal disclaimer.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

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SWL

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June 3, 2002

Karen Cochran (Cochran?)

KAREN COCHRAN, PERSON, PH.D.
PRIMARY EXAMINER